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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,750	03/31/2005	Hitoshi Arai	00005.001251	6890

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EXAMINER	
JAISLE, CECILIA M	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/516,750	ARAI ET AL.	
	Examiner	Art Unit	
	Cecilia M. Jaisle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/06/04 & 03/31/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 39-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28 and 39-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to bicyclic pyrimidine derivatives, their quaternary ammonium salts and their pharmaceutically acceptable salts, classified in various subclasses in class 544.

II. Claim 28, drawn to pharmaceutical compositions comprising a bicyclic pyrimidine derivative, a quaternary ammonium salt thereof or a pharmaceutically acceptable salt thereof, classified in various subclasses in class 424.

III. Claim 39, drawn to a method for treating inflammation, classified in various subclasses in class 514.

IV. Claim 40, drawn to a method for modulating the TARC (CCL17) and/or MDC (CCL22) function, classified in various subclasses in class 514.

V. Claim 41, drawn to a method for treating and/or preventing a disease that is related to TARC (CCL17) and/or MDC (CCL22), classified in various subclasses in class 514.

VI. Claim 42, drawn to a method for preventing a disease that is related to T cells, classified in various subclasses in class 514.

VII. Claim 43, drawn to a method for treating and/or preventing an allergic

disease, classified in various subclasses in class 514.

The inventions are independent or distinct for the following reasons. Inventions I - VII, respectively, are not obvious variants of each other, i.e., a reference that could be used to reject one invention could not be used to reject another invention; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the compounds of Group I are distinct from the pharmaceutical compositions of Group II and from the methods of Groups III and VII, because the compounds of Group I would be expected to be useful as antipsychotic agents (WO97/47601). The pharmaceutical compositions of Group II are distinct from the methods of Groups II-VII, because the pharmaceutical compositions of Group II would be expected to be useful in useful in antipsychotic methods.

In the instant case, the related inventions of Groups I – VII, respectively, do not overlap in scope because the inventions of Groups I – VII represent different types of inventions and different functions, as evidenced by their separate classification in the art. Therefore, it would impose an undue burden on the examiner to search and examine these distinct inventions together.

Because these inventions are independent or distinct for the reasons given above and have acquired separate status in the art in view of their different classification and require different fields of search (see MPEP § 808.02), restriction for

examination purposes as indicated is proper.

Claims of this application are directed to the following patentably distinct species: compounds, pharmaceutical compositions and methods having compounds in which:

m = 1 and n = 1, classified in class 544, subclass 280,

m = 1 and n = 2, classified in class 544, subclass 279,

m = 1 and n = 3, classified in class 544, subclass 279,

m = 2 and n = 1, classified in class 544, subclass 279,

m = 2 and n = 2, classified in class 544, subclass 279, and

m = 3 and n = 1, classified in class 544, subclass 279;

and further compounds in which R_2 represents:

the moiety defined as (i) in claim 1, classified in various classes in class 544,

the moiety defined as (ii) in claim 1, classified in various classes in class 544,

the moiety defined as (iii) in claim 1, classified in various classes in class 544, and

the moiety defined as (iv) in claim 1, classified in various classes in class 544.

The species are independent or distinct because compounds in which m = 1, n = 1 and R_2 represent the moiety defined as (i) in claim 1 would be expected to be useful as protein kinase inhibitors (US Pat. No. 7,091,208). In addition, the various species of compounds in which m, n and R_2 are the moieties defined above would each have separate patent classification and would each be separately searched in the literature.

A complete reply to this requirement must include (i) an election of an invention

to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. Applicants are also required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-28 and 39-43 are generic.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction and election of species requirements, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record

showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product, pharmaceutical composition and method claims. Where applicants elect claims directed to the product, and the product claims are subsequently found allowable, withdrawn composition and method claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected invention must require all the limitations of an allowable product claim for that invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined claims will be withdrawn, and the rejoined claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found

allowable, an otherwise proper restriction requirement between product, composition and method claims may be maintained. Withdrawn claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicants are advised that the withdrawn claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle, J.D.

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